

ATTACHMENT 7

DOCKET NO: ANIT0018U-US
IN RE APPLICATION OF: Pimentel
APPLICATION: 09/226,597 filed 1/7/1999
TITLE: Weight Control Using An Anti-Lapse Antibody
EXAMINER: Gailene Gabel
GROUP ART UNIT: 1641
CONFIRMATION NO: 9844

37 CFR 1.132 DECLARATION OF JULIO PIMENTEL

1. I have a Ph.D. in Nutritional Science from the University of Wisconsin, in May, 1991.
2. I am the inventor of the inventions disclosed in US patent applications 09/226,597 filed 1/7/1999 and 08/888,202 filed July 7, 1997.
3. I have reviewed USP 5,827,517, USP 5,989,548, and USP 6,793,921.
4. Result of tests presented in USP 6,793,921 and USP 5,827,517 show no efficacy for antibodies to certain other nutrition related factors, other than CCK. That test data shows that some of the antibody treatments were effective, and some were not effective.
5. USP 5,827,517 reports in its example 9 (spanning columns 9 and 10) on the feeding of *antibodies* to Bombesin, Motilin, and Neuropeptide Y. (Note the title of example 9: "Feeding Anti-Peptides to Broiler Chicks". The example 9 results at column 10 lines 50-55 refer to the peptides, which appears to be short hand for the tested anti peptides.) Of those three, only antibodies to Neuropeptide Y had an effect on weight gain or feed conversion efficiency differing from the control group. Thus, antibodies to all but one of the nutritional factors tested in USP 5,827,517, failed to show any effect. Moreover, that is despite the strong effect the *actual* nutritional factors (not antibodies to those factors) had on weight gain or feed conversion efficiency, noted in USP 5,827,517's example 12 at columns 13 and 14.
6. Similarly, USP 5,989,548 shows that feeding antibodies to Bravo provided no substantial effect compared to the control group. See USP 5,989,548 example 11 in columns 11 and 12.


7. Similarly, USP 6,793,921 also shows the unpredictability in this area of technology. It states that:

The present invention was made based on the above discovery suggesting that antibodies against whole cells of Hp are not sufficient and antibodies against urease of Hp and/or flagella of Hp are effective for completely inhibiting the colonization of Hp in gastric mucosa to inhibit the growth of Hp in the stomach. It was further found that the combination of each or both of these antibodies and at least one organism selected from lactic acid bacteria, Enterococcuses, yeasts and Bacillus has a synergistic effect.

The point of this disclosure is that "antibodies against whole cells of Hp [H. pylori; a bacteria in the lining of the stomach] are not sufficient " indicating that an antibody to yet another factor present in digestive systems was ineffective.

8. I swear under penalty of perjury of the laws of the United States that the foregoing is true and correct.

12-14-06
Date



Julio Pimentel

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December 14, 2006 (3:10pm)

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